

K061695

## 5. 510(K) SUMMARY

SEP 14 2006

Model : LED Prolux 770,

### 510K:

- Submitted by: PENG LIM ENTERPRISE CO., LTD.  
67 HWA RONG RD., 2F, KU SHAN DIST.,  
KAOHSIUNG, China (Taiwan))
- Contact person: Mr. C. WANG  
PENG LIM ENTERPRISE CO., LTD.  
67 HWA RONG RD., 2F, KU SHAN DIST.,  
KAOHSIUNG, China (Taiwan)
- Date Summary Prepared: May 8, 2006
- Classification name: Activator, Ultraviolet, for Polymerization
- Classification number: *EBZ, Class II*
- Regulation Number: 872.6070
- Proprietary name: *LED PROLUX 770*
- Common name of device: *CURING LIGHT*
- Predicate Device: *Apoza Enterprise CO., Ltd.*  
*LED Turbo*  
*510K No – K040618*

**Statement of Intended Use:** This LED Prolux 770 is a visible curing unit designed for polymerization of light cured materials used by dental professionals..

**Comparison to Predicate Devices:** The This LED Prolux 770 is a visible curing unit designed for polymerization of light cured materials used by dental professionals. It has been carefully compared to legally marketed device with respect to intended use and technological characteristics. In addition, performance testing has been done to validate the performance of the device. The comparison and validation results presented in this 510k notification to the FDA show that the subject device is substantially equivalent to predicated device and are safe and effective in its intended use.

We believe that the LED Prolux 770 is substantially equivalent to the predicate device, i.e., Apoza LED Turbo in K040618, and the data provided support the safety and effectiveness of LED Prolux 770 for the intended uses.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 14 2006

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. C. S. Wang  
Peng Lim Enterprise Company Limited  
67 HWA Rong Road, 2<sup>nd</sup> Floor  
Ku Shan District,  
Kaohsiung 804,  
CHINA (TAIWAN)

Re: K061695

Trade/Device Name: LED Prolux 770  
Regulation Number: 21 CFR 872.6070  
Regulation Name: Ultraviolet Activator for Polymerization  
Regulatory Class: II  
Product Code: EBZ  
Dated: September 3, 2006  
Received: September 8, 2006

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

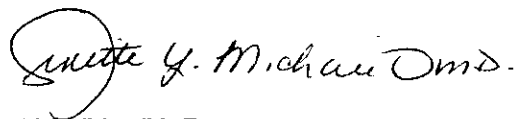
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin, Ph.D.", written in a cursive style.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital.

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510 (K) Number ( If Known ): K01695

Device Name: *PENG LIM Enterprise Co., Ltd.*

*LED Prolux 770*

● *Indications for use:*

*This LED Prolux 770 is a visible curing unit designed for polymerization of light cured materials used by dental professionals.*

Prescription Use ✓

AND/OR

Over-The-Counter Use       

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Signature Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510 (K) Number: K01695

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